UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,835	08/04/2003	Tedd E. Elich	9280.2	5061

20792 7590 10/31/2007

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,835	ELICH ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4-7, 9 and 16-22*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-10, 12-13, 16-25* is/are pending in the application.

4a) Of the above claim(s) *4-7,9 and 16-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,10,12,13 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's, response filed on 1/11/07 is acknowledged and entered. Accordingly , the examiner is issuing a non- final rejection .

Status of Claims

2. No claims have been amended or canceled.

Claims 1, 2, 3, 8, 10 ,12 , 13 and 23-25 are under examination with respect to SEQ.ID.NO: 2.

Claims 4-7, 9 and 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non elected inventions.

35 USC 112, first paragraph maintained

3. The written description rejection of claims 1, 2, 3, 10 ,12 , 13 and 23-25 under 35 USC 112, first paragraph is maintained as set forth in the previous office action.

Claims 1, 2, 3, 10 ,12 , 13 and 23-25 are drawn to a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide binds to soraphen, said peptide is a monomer and has a soraphen dissociation constant of from 10^{-7}-10^{-14}, wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase, wherein said carboxylase is Ustilago maydis carboxylase Or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, wherein said functional biotin carboxylase domain binds to soraphen , wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase, wherein said carboxylase is Ustilago maydis carboxylase. These claims are directed to a genus of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide binds to soraphen. The specification teaches the structure of only a single representative species of a peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2, wherein said functional biotin carboxylase domain binds to soraphen. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement

such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.
Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.
The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).
The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. Thus, the instant specification may provide an adequate written description of the a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, wherein said functional biotin carboxylase domain binds to soraphen , wherein said ACCase is selected from the group consisting of mammal, insect, yeast, Ascomycota, Basidiomycota, and Oomycota ACCase, per Lilly by structurally describing a representative number of "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."
In this case, the specification does not describe a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain,, nor does the specification

provide any partial structure of such a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain,, nor any physical or chemical characteristics nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2, wherein said functional biotin carboxylase domain binds to soraphen, this does not provide a description of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, that would satisfy the standard set out in Enzo.
The specification also fails to describe a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain by the test set out in Lilly. The specification describes only a single peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."
Thus, the specification does not provide an adequate written description of a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen or a peptide consisting essentially of a functional Acetyl CoA carboxylase (ACCase) biotin carboxylase domain that is required to practice the claimed invention. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicant argues 8/13/07 that the limitation "deleted" does not limit the claim to only BC domain of ACCase but includes an ACCase containing more of the sequence than the BC domain, but the other domains are rendered non-functional using common molecular biology techniques.

The argument has been considered but found to be non-persuasive because the specification on page 6 recites that the terms "deleted" or "deletion" means total deletion of the specified segment. Further the argument that the other domains are not functional etc are not set forth in the claim.

Applicant states that contrary to the assertion in the Action, Applicants provide multiple examples in the specification, SEQ ID NOS:2, 4, 6, 8, 10, 12, 14, or 16 and are representative examples of ACCase peptides having a deleted biotin binding domain, having a

deleted carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide binds to soraphen as claimed .

The argument has been considered but found to be non-persuasive because the specification teaches only a single peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2 from *Ustilago maydis* carboxylase and does not teach other species comprising a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen from *Ustilago maydis.*

Applicant states that Acetyl CoA carboxylase (ACCase) from different organisms are known in the art and one of skill would clearly understand what was encompassed by a peptide comprising an Acetyl-CoA carboxylase having a deleted biotin binding having a deleted carboxy transferase domain, and having a functional biotin carboxylase domain, wherein said peptide binds to soraphen.

The argument has been considered but found to be non-persuasive because the examiner did not indicate that Acetyl CoA carboxylase (ACCase) from different organisms are unknown but indicated that a single peptide consisting of Acetyl CoA carboxylase (ACCase) biotin carboxylase domain, SEQ.ID.NO:2 from *Ustilago maydis* carboxylase has been disclosed but not " a peptide comprising an AceCoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase that binds to soraphen" as it reads on diverse species of Acetyl CoA carboxylase.

Applicant brings examiner's attention to the case law *Invitrogen Corp. v. Clontech Laboratories, Inc.,* (429 F.3d 1052, 77 U.S.P.Q.2d 1161 (Fed. Cir. 2005)) that such a claim can satisfy the written description requirement.

The argument has been considered but found to be non-persuasive because the independent claim in *Invitrogen Corp. v. Clontech Laboratories, Inc., recites the* isolated DNA molecule is derived from a Moloney murine leukemia virus (M-MLV) nucleotide sequence. *Id.* at 1074. However, the present claim neither recites the source of the peptide nor the structure of the peptide (SEQ.ID.NO:2).

Claim Rejections - 35 USC 102 maintained

6. The rejection of claims 1 -3 , 10 , 12 and 23-25 under 35 U.S.C. 102(b) as being anticipated by Bailey et al Mol Gen Genet (1995) 249: 191-201(IDS 11/17/03) is maintained for the same reasons as set forth in the previous office action.

Applicant argues 8/13/07 that the structural details of a peptide that binds to soraphen are disclosed in SEQ.ID.NO:2, 4 etc.

The argument has been considered but found to be non-persuasive because the claim1 does not set forth any structural details of a peptide that binds to soraphen, SEQ.ID.NO:2.

Applicant argues 8/13/07 that the reference does not teach each and every limitation. Bailey does not teach dissociation constant and Shen et al (reference filed by the applicant on 1/11/07) shows that the BC domain discussed in Bailey does not inherently disclose the dissociation constant.

The argument has been considered but found to be non-persuasive because Bailey teaches ACCase from *Ustilago maydis* which contains BC domain that binds to soraphen. In the absence of evidence to the contrary that it binds t soraphen at the same dissociation constant as claimed. *Further, Shen et al do not cite Bailey and do not indicate that the dissociation constant is not inherent.* As the claim 1 recites "comprising" it reads on ACCase full length protein that has soraphen binding site.

Applicant further argues that that full length ACCase is known and the applicant's invention is recombinant BC domain of the invention is much more stable and can be expressed in much higher level etc.

The argument has been considered but found to be non-persuasive because the claims do not set forth ACCases consisting of BC domain SEQ.ID.NO:2 from *Ustilago maydis.* In the absence of such structural details the art reads on the claimed invention.

7. The rejection of claims 1-2, 10 , 12 and 23-24 under 35 U.S.C. 102(b) as being anticipated by Schulte et al 1997 Proc. Natl. Acad. Sci. USA Vol. 94, pp. 3465-3470 is maintained for the same reasons as set forth in the previous office action.

Applicant argues that lime Bailey Schulte et al do not teach that the peptide binds to soraphen with the claimed dissociation constant and what portion of BC domain is represented in the dendogram.

The argument has been considered but found to be non-persuasive because the claims as set forth do not recite the BC domain structure. Therefore, in the absence of such structural details the art reads on the claimed invention and inherently comprises the claimed dissociation constant.

Applicant argues that A1-Feel et al reported the gene having a putative Biotin Binding ("Biotin Binding Site") and a Carboxytransferase ("Transcarboxylase") domain. Therefore,

neither Schulte et al or A1-Feel did not teach of an ACCase having a deleted Biotin Binding domain and deleted Carboxytransferase domain.

The argument has been considered found to be non-persuasive because, recitation of "comprising " in the claim is not limited to only BC domain but also reads on ACCase.

8. The rejection of claims 1 -3 , 10 , 12, 13 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Bailey or Schulte et al and each in view of Trubetskoy et al U.S.Patent 7,098,032 is maintained for the same reasons as set forth in the previous office action.

Applicant sates the Bailey or Schulte et al do not read on the claimed invention , therefore, the 103 rejection should be withdrawn.

The argument has been considered found to be non-persuasive because Bailey or Schulte et al have been discussed and the rejections have been maintained as set forth above.

Remarks

9. No claims are allowed.

This application contains claims 4-7, 9 and 16-22 drawn to an invention nonelected. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on (571) 272-0974. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600